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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. 10/512,097 05/17/2005 Per Sjorup P08422US00/MP 9110 **EXAMINER** 881 7590 07/26/2006 STITES & HARBISON PLLC HAMIDINIA, SHAWN A 1199 NORTH FAIRFAX STREET ART UNIT PAPER NUMBER SUITE 900 1653 ALEXANDRIA, VA 22314 DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/512,097	SJORUP, PER
	Examiner	Art Unit
	Shawn Hamidinia	1653
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
<ul> <li>1) Responsive to communication(s) filed on <u>03 May 2006</u>.</li> <li>2a) This action is FINAL.</li> <li>2b) This action is non-final.</li> <li>3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ul>		
Disposition of Claims		
<ul> <li>4)  Claim(s) 1-6 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-6 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>		
Application Papers		
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

#### **DETAILED ACTION**

1. This office action is in response to the amendment filed May 3, 2006. Claims 1-5 are currently rejected. Claim 6 is newly added.

## Maintenance of Rejections

- 2. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lilja et al. (1994).
- 3. Claims 1-5 are rejected under 35 U.S.C. 103(a) as obvious over Lilja et al. in view of Haack et al. (1984).

#### Response to applicants' arguments

4. Applicants assert that Lilja et al. do not anticipate the present invention because individually or in combination with Haack et al, do not teach or suggest defattening a rind using steam and/or hot water. Applicant further argues that Lilja, individually or in combination with Haack, fails to teach or suggest defattening a rind using hot water or steam prior to hydrolysis as instantly claimed. Applicant points out that Lilja et al. teach an optional defattening step and mixing the ground collagen-containing raw material with water to form a slurry.

Applicants also argue that nowhere in Haack or Lilja is there a suggestion to motivate one of ordinary skill in the art to use hot water or steam in a method to defatten the rind prior to hydrolysis. Moreover, applicants claim that Lilja is not an enabling reference to anticipate the present invention without undue experimentation in order to use rind as a collagen-containing starting material. Applicants further introduces newly added claim 6, which is directed to cutting or chopping a rind into pieces not less than 1 mm.

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Applicants' assertions are not found persuasive because Lilja et al. teach mixing the ground raw material with water to form a slurry, and then subjecting the slurry to a temperature of 60-130°C for a time of 1 second to 1 hour, (see lines 8-27, page 5). Subjecting a slurry, comprising water, at these high temperatures reads on a method wherein the ground material is extracted with hot water and/or steam. Furthermore, Lilja et al. teach that the raw material may be defatted prior to grinding, (see lines 9-12, page 7). Since Lilja et al. teach that the raw material may be defatted prior to grinding, and the grinding step is prior to hydrolysis by acid, it logically follows that Lilja et al. teach a method for defatting the raw material prior to hydrolysis, (refer to lines 8-27, page 5).

Applicants assert that there is no motivation to combine Lilja et al. and Haack et al.; this is found unpersuasive. Lilja et al. teach that the collagen-containing raw material may optionally be defatted prior to grinding, and provides the motivation to

combine the defatting pork rind teachings of Haack et al. by stating that, "although such a step is not critical, a low fat content facilitates subsequent process steps." (see lines 9-12, page 7). Although Lilja et al. teach that the defatted raw material step is optional, it states that such a step facilitates subsequent process steps which reads on claim 1.

Applicants' assertion that Lilia et al. is not an enabling reference is found unpersuasive. Contrary to applicants' assertion, Lilia et al. specifically teach presentday methods for producing gelatin distinguish between whether the raw material employed is bone or hide (split, rind) and other connective-tissue material, (see lines 35-37, page 2 to lines 1-2, page 3). Lilja et al. teach that containing no minerals, hide and connective tissue are not subjected to any demineralization, but are otherwise treated in the same way as bone raw material, (see lines 3-5, page 3). Lilja et al. further teach that their inventive method can be applied to different collagen-containing materials, such as hides, split, rind, sinews, intestines, stomachs, connective-tissue material, and different types of bone material from animals, (see lines 28-32, page 5). Thus, applicants' assertion that Lilia et al. would require undue experimentation in order to use rind as a collagen-containing starting material is unpersuasive because Lilia et al. teach that other than demineralization, hide (split, rind) is treated the same as bone raw material, and hence would not require undue experimentation to use rind as a collagencontaining starting material.

Consequently, Lilja et al. teach all the elements of claims 1-5 and therefore these claims are anticipated under 35 USC § 102(b), and also under 35 USC § 103(a) as obvious over Lilja et al. in view of Haack et al.

### New Rejections

### Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 6. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 6 is directed to the method of claim 1, wherein cutting or chopping comprises cutting or chopping a rind into pieces not less than 1 mm.

  However, cutting or chopping a rind into pieces not less than 1 mm is not disclosed in the specification, and is therefore new matter. Page 1, lines 30-31, of the specification merely states that if the rind is sufficiently comminuted, e.g. in pieces of 1 mm, the hydrolysis may also be carried out. There is no mention of preferably cutting a rind into pieces not less than 1 mm. The only other reference to the size of rind pieces is in the example on page 2 of the specification which describes that rind is cut into pieces of

approximately 5 mm, (lines 21-22, page 2). Thus, the specification does not teach chopping rind into pieces greater than 1 mm.

#### Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lilja et al. in view of Haack et al.

Lilja et al. teach a method for producing gelatin in claim 1 from collagencontaining raw materials such as hide (split, rind) and other connective-tissue material
(see lines 35-2, page 2-3) comprising the following steps: a) grinding the raw material to
a particle size not exceeding 1 mm, b) mixing the ground raw material with water to form
a slurry, c) subjecting the slurry from step b), in optional order, to an adjustment of the
pH to 2-5 and to an adjustment of the temperature to 60-130 °C for a time from 1 s to 1
h, d) adjusting the temperature of the slurry once more, f) adjusting the pH of the slurry
or the liquid portion by using an alkaline chemical such as calcium hydroxide (see lines
26-34, page 9), and g) recovering the gelatin from the liquid portion in filtering steps
and/or other cleaning steps.

Haack et al. teach that defatted pork rind granules are useful in the manufacture of gelatin, see abstract. Haack et al. further teach that his method includes defatting the rind before acid hydrolysis for manufacture of the gelatin product, (see Figure 4, page 5-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to follow the method by Lilja et al. for producing gelatin by grinding the collagen-containing raw material not exceeding 1 mm, defat pork rinds before hydrolysis of the gelatin product following the teachings of Haacke et al. with the expectation of enhancing the production yield of gelatin.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to cut rind into a size not exceeding 1 mm or into whatever size pieces necessary in order to carry out the method for producing gelatin taught by Lilja et al.

#### Conclusion

- 9. No claim is allowed.
- 10. Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawn Hamidinia whose telephone number is (571) 272-4534. The examiner can normally be reached on Mon-Fri from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SAH

ROBERT A. WAX